Specification

Please amend the specification as follows:

At page 1, line 15 amend 2,5 to 2.5

At page 2, line 28 amend "advantage being manifest particularly" to advantage is manifested particularly.

REMARKS

Claims 13-19 are pending in the instant application. Applicants have not raised any issues of new matter.

Claims 13-19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-23 of U.S. Application No. 10/754,685, and over claims 13-20 of U.S. Application No. 10/754,733.

Claims 13-19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,514,958, and over claims 1-11 of U.S. Patent No. 6,399,594.

Applicants will submit terminal disclaimers to overcome such rejections as both this application and the cited applications and patents are commonly owned by the same assignee.

SPECIFICATON

The Examiner has alleged that the incorporation by reference of EP 389 035 is improper. Applicants respectfully traverse that rejection. The incorporation by reference of EP 389 035 is for the general information of compositions having tibolone with a pharmaceutically acceptable solid carrier, not as a limitation on the invention.

Applicants will amend the specification in reference to the trademark LIVIAL® prior to issuance of this application.

35 U.S.C. 103 REJECTION

The Examiner alleges that the present invention is obvious in view of Kelder et al. (US 4,701,450) taken together with Deckers et al. (EP 0613687), 'Stedman's Medical Dictionary' (1972, page 589),'Handbook of Pharmaceutical Excipients' (1986, pages 108-110, 259-260 and 289-293), Loliger et al. (US 5,364,886) and Sas et al. (EP 389035).

Applicants respectfully traverse this objection. The present application relates to capsules with 0.1 to 10 % by weight tibolone and having a carrier having at least 47 to 90 % by weight of lactose, resulitng in unexpected stability.

The Examiner has pointed to the many elements missing from the disclosure in the cited prior art and then using impermissible hindsight, attempts to reconstruct the invention from the prior art. There is nothing in the teachings of the cited prior art that in anyway address the question of improved stability and/or storage. One looking to the question of stability and/or storage would not be led to the cited prior art to solve the problems with regard to such stability and/or storage.

The Applicant fails to see in any of the cited documents, either alone or in combination, teaching or suggestion of the capsule of the subject application with a carrier having at least 47 to 90 % by weight of lactose and 0.1 to 10 % by weight tibolone. The resulting capsules, comprising tibolone with improved stability, are illustrated at least by comparing Example 3 (page 8) and Example 7 (page 10) of the subject application.

Kelder et al. (US 4,701,450) teaches that pharmaceutically acceptable carriers comprising tibolone can be composed of one or more of a number of possible ingredients (col.3, lines 7-16). Applicant fails to see in Kelder et al. any teaching or suggestion of improved stability of the pharmaceutical dosage unit of the current invention resulting from the carriers comprising at least 47-90% by weight of lactose in the carrier of a 0.1 to 10 wt.% tibolone capsule as instantly claimed.

Further, at least for the reasons below, even assuming arguendo the combination of the other references with Kelder et al., the deficiencies of that reference are not cured.

Deckers et al. (EP 0613687) discloses pregnane derivates (including tibolone) for the treatment of tumors. Example 1 of Deckers et al. discloses a preparation tablet comprising tibolone with starch and lactose. However, Applicants fail to see any teaching or suggestion of a capsule comprising 0.1 to 10 weight % tibolone and at least 47 to 90 weight % lactose, or an indication of the resulting stability.

As to the Examiner's assertions with respect the 'Handbook of Pharmaceutical Excipients', Applicant fails to see any teaching or suggestion of use of starch in combination with lactose to impart improved stability to pharmaceutical formulations, let alone to pharmaceutical formulations of tibolone. Hence the "Handbook" does not remedy the deficiencies of Kelder et al.

Turning to Loliger et al. (US 5,364,886) and Sas et al. (EP 389035), Applicant fails to see any teaching or suggestion of the required use of 47 to 90% by weight lactose in the carrier. Thus the requirements lacking in Kelder et al. are not cured by these references.